SANDIA NATIONAL LABORATORIES
CIVILIAN RADIOACTIVE WASTE MANAGEMENT
QUALITY ASSURANCE IMPLEMENTING PROCEDURE (QAIP)

QAIP 20-1

TECHNICAL PROCEDURES

Revision 08

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REVISION HISTORY

Revision	Summary
00	Initial Issue.
01	Note 1 was added to Section 4.2 to explain what editorial corrections consist of, how they could be made, and what reviews were required. This implemented details from the QARD.
02	Sections 4.4 and 6.0 and Appendix A were modified to clarify the review and approval process for TPs, incorporate a new requirement concerning responsibility for data reduction and transfer, and to update titles in the "References" section.
03	Modifications were made to sections 4.1, 4.2, 5.0, and Appendix A to clarify how to document modifications to the process specified in a nationally-recognized standard, and to include a "Rationale for Revision" for each TP change.
04	Body of procedure put in playscript format; Revision History incorporated replacing "Rationale for Revision" form; and other modifications necessary to incorporate changes in requirements (QARD Revision 5). Corrective action resulting from Deficiency Report YMQAD-96-034 implemented to clarify records status of review comments.
05	Changes to section 4.2, 5.0, and Appendix A in response to Deficiency Reports YM-96-D080 and YM-96-D088. Concerning expedited changes, clarified that the PI is the authorizing "level of management", specified a time limit for completion of a formal change subsequent to an expedited change, specified a methodology for evaluation of the effect of a formal change differing from an expedited change, and specified that a memo or an e-mail is to be the mechanism for notifying concerned parties about expedited changes. Requires retention of mandatory comment records in section 4.1. Defines record retention period for records generated by this QAIP. Clarified in Appendix A that TPs must cite QAIP 17-1 for records submittal and that records resulting from activities governed by TPs are lifetime (QA:L) records.
06	Reformatted for consistency with other QAIPs, deletes reference to QAIP 2-5, and clarifies record processing.
07	Revised for consistency with Process Validation and Re-engineering procedure changes.
08	Revision to delete requirements to AP-2.14 Review of Technical Products, AP-6.1Q Controlled Documents, and to meet format criteria of QAIP 5-1.

TABLE OF CONTENTS

1.0 PURPOSE AND SCOPE

The purpose of this Sandia National Laboratories (SNL) Civilian Radioactive Waste Management (CRWM) procedure is to define the process for preparing, revising, and approving Technical Procedures (TPs) used in scientific investigations.

This procedure details the requirements for preparation and use of TPs and applies to SNL CRWM staff and others who plan, prepare, and conduct, and oversee scientific investigations.

In general, TPs are required for those portions of scientific investigations wherein personnel perform repetitive operations/activities (e.g., the operation of specific equipment or equipment systems used in scientific investigations, or data collection activities involving several replications).

2.0 DEFINITIONS

Technical Procedure (TP): Detailed implementing procedure consisting of a set of written instructions defining technical requirements; constraints; the type, range, and accuracy of measuring devices; and the procedural steps to accomplish a particular task.

3.0 PROCEDURE

3.1 Preparation, Review, Approval, and Issuance of TPs

3.1.1 The Author prepares a TP to address all content topics shown in Appendix A. The format of the TP cover sheet should follow that of the cover sheet for this procedure, with "Technical Procedure" in place of "Quality Assurance Implementing Procedure," followed by the appropriate TP title and TP plus the appropriate number entered in place of QAIP 20-1. The TP number is an Arabic numeral that provides a unique identification and is obtained from the SNL YMP Document Control staff. Each page of a TP should bear the following header, located in the upper right-hand side of the page:

TP (Number)

Revision (Number)

Page (Number) of (Total Number)

The TP will have a Revision History immediately following the cover page that provides a description of the changes made to the TP, clearly indicating the source of the changes (procedure improvement, resolution of a deficiency, planning document change, etc.).

3.1.2 The author shall sign and date the procedure cover sheet and forward the procedure to the assigned reviewers as follows in this section. Obtain reviews from the following individuals as a minimum: the Prinicipal Investigator (PI) for the activity (if the author is not the PI), a technical reviewer, and a QA reviewer.

3.1.3 The reviewers shall clearly and legibly write all comments on the procedure or revision or indicate that there are no comments. Indicate mandatory comments with an asterisk. Reviewers shall sign the procedure or revision for approval.

3.1.4 The PI (if different than the author) reviews to ensure the TP addresses planning objectives.

3.1.5 The Technical Reviewer shall review the procedure to ensure technical adequacy, correctness, and completeness. (The technical review may be performed by the PI, if the PI is not the author.)

3.1.6 The Quality Assurance (QA) Reviewer shall review the procedure to assure that appropriate quality requirements and controls are included.

3.1.7 For each review, the Author shall resolve comments and incorporate the applicable responses in the procedure or revision.

3.1.8 The PI enters the effective date on the procedure.

3.1.9 Forwards the approved procedure or revision, a copy of the procedure in an acceptable word processing format, and review documentation to the Document Control staff for distribution and processing.

3.2 Changes

3.2.1 Upon identifying the need for a procedural change, the Author shall draft the procedure change(s) and revise the procedure. For all procedure revisions provide a description of each change in the Revision History. Review the Revision History each time a revision is proposed, to ensure that commitments are not inadvertently deleted.

NOTE 1: Editorial corrections may be made to documents without being subject to review requirements. The following items are examples of editorial corrections:

a) Correcting grammar or spelling,
b) Renumbering sections or attachments in a way that does not affect the sequence of work,
c) Changing the title or number of the document, and
d) Updating organizational titles (not responsibilities).

Editorial changes shall be approved by the PI.

NOTE 2: If a user of the procedure determines an activity cannot be performed as listed and the change process would cause unreasonable delays, then an EXPEDITED CHANGE may be requested by performing the following steps:

a) The user contacts the responsible PI (who is the “level of management” authorized to approve expedited changes).
b) The PI reviews the nature of the change required and either authorizes an expedited change or shall stop work until the procedure is revised.
c) If an expedited change is authorized, the procedure is changed at the work location by taking the following steps:
    1) On a copy of the current controlled version of the procedure, draw a single line through the text to be changed.
    2) Insert the corrected text above or adjacent to the text being changed.
    3) Initial and date the change.
    4) Notify the PI of the change completion.
d) In a timely manner, notifies other affected personnel, as necessary, of the expedited changes via memorandum or e-mail.
e) Shall process an expedited change through the formal revision process within 30 working days of the approval of the expedited change. If the formal revision process results in change that is different from the expedited change, the results

of the work activities performed under the expedited change shall be evaluated by comparing those results with the projected results had the activities been performed as the formal revision specifies. The results of the evaluation are documented and included with the approved revision and review documentation and forwarded for processing by Document Control.

4.0 RECORDS

The following QA records and record packages, including corrections and changes thereto, are prepared and submitted to project records in accordance with AP-17.1Q by Document Control staff upon issuance as a controlled document. These QA records include:

The approved procedure or revision

Copies of the procedure or revision containing reviewer's comments

Documentation of the evaluation resulting from differing expedited and formal revisions to a TP

5.0 REFERENCES

AP-17.1Q, "Record Source Responsibilities for Inclusionary Records"

6.0 APPENDICES

Appendix A. Technical Procedure Content (1 page)

TECHNICAL PROCEDURE CONTENT

(QAIP 20-1, Rev. 08, Appendix A)

The topics listed below shall be included in Technical Procedures (TPs), as appropriate. Many of the following requirements for a scientific investigation may already be addressed in planning documents and need not be repeated in the TP. Conversely, some of these topics may be addressed in planning documents, but in a less-detailed manner than is needed in a TP. In such cases, the author may include as much detail as deemed necessary in the TP.

1. Objectives and the primary tasks involved (including sequencing, if appropriate).
2. Acceptance criteria sufficient for determining that activities were satisfactorily accomplished.
3. Personnel responsibilities.
4. Reference to any applicable nationally-recognized standards and criteria (e.g., ASTM or ISRM Standards).
5. Reference to the appropriate implementing documents (e.g., other TPs). Reference to the appropriate planning documents and the identification of associated investigative activities.
6. A description of the laboratory and/or field testing equipment.
7. The identification of computer software.
8. The necessary prerequisites (e.g., calibrated instrumentation, personnel familiarization), special controls, precautions, environmental conditions, process parameters, and/or skills.
9. Methods of identifying, recording, and documenting data to provide traceability, indicate usability, document validation status, and any applicable Project Data Archive Data-Set identification number.
10. Identify methods on how data reduction and transfer shall be controlled to permit independent reproducibility by another qualified individual.
11. Instructions for addressing accuracy, precision, and representativeness of the results (or a detailed reference to appropriate study plan that discusses this issue).
12. A sequential description of the actions to be taken (scientific approach or technical methods used) including the quality assurance program verifications and hold points to overview the work.
13. Controls for altering the sequence of required operations.
14. The required records generated by the TP and method for the recording of objective evidence of the results of the work performed, for example, data collection forms specified by the TP, data acquisition system printouts, sample control documentation (e.g. chain of custody forms), instrumentation calibration/calibration check records, etc. Also included would be documentation of the evaluation of the results of activities governed by the TP if there is a difference between an expedited change to a TP and the subsequent resulting “formal” revision. This section shall require that records be submitted in accordance with AP-17.1Q and/or AP-SIII.3Q and that they be designated QA:QA.